UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,551	02/14/2002	Matthew Lawrence Lynch	8422M	8636

27752 7590 08/10/2004

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER	
SADULA, JENNIFER R	

ART UNIT	PAPER NUMBER
1756	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,551	LYNCH ET AL.	
	Examiner	Art Unit	
	Jennifer R. Sadula	1756	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11, 13-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following Office Action is a complete response to the amendment and arguments filed 3/24/04.

Response to Amendment

Applicant's amendments filed 3/24/04 have been fully considered and have overcome the objections to the drawings and subsequent objections to the spec. The 112 rejections have been amended to be objections to the specification to merely point out Applicants inconsistencies and how the Examiner has now interpreted them. The amendment to the claims has necessitated making the application final under this rejection.

Information Disclosure Statement

With regard to the filing of the IDS it is unclear to the Examiner- does the Applicant merely want the table of contents considered for these two references?

Specification

The disclosure is objected to because of the following informalities: Page 4, line 28 of the spec- the new reference is made to the lower range of "b", and Examiner notes that the "greater than" symbol is an underlined addition and is not representative of a "greater than or equal to" symbol. This is further made clear by Applicants' other amendments. Therefore Examiner further notes that the "optional polar solvent" is not optional at all but rather required as it is never specified that b=0 as an option.

Claim Objections

It is noted that Claim 1 states that "b" is an "optional solvent" the limit for "b" has now been examined in terms of 1.0>b>0. Appropriate correction was required to amend b to include times when b=0, however the Applicants have chosen not to do this and further not to amend the specification accordingly. Therefore Examiner further notes that the "optional polar solvent" is not optional at all but rather required as it is never specified that b=0 as an option. Thus the Examiner requires that the word "optional" be removed in line 6 of the claim (and any subsequent reference) to alleviate further confusion on this matter.

In the newly added claims it is unclear why there are underlined portions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 4-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-12 and 15-19

of U.S. Patent No. 6,656,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the application claims and the patented claims are that the application claims the invention more narrowly than the patented claims. The application claims, while being narrower, are fully disclosed by the patent specification as design modifications of the generic groups. Therefore it appears to the Examiner that this application is merely an attempt to extend Applicants coverage monopoly and not an attempt to patent a new invention.

More specifically, Claim 1 in the application is a cubic liquid crystalline phase precursor comprising an amphiphile comprising a monoglyceride, a polar solvent, and an additive selected from the group wherein the mass fractions of the components are the same as those in the patent. Because the Application contains "comprising" language it is clear the composition is not limited from containing a hydrotrope, which is the only different generic component found in the patented claims. Claim 1 (and subsequently claim 21) of the Application corresponds to claim 1 of the patent. Claims 2 and 4-11 (and subsequently claims 22-26) of the Application correspond to claims 3-6, 9-12 and 14-15 of the patent. Claims 14-15 of the Application correspond to claims 17-18 of the patent. Claims 16-17 of the Application correspond to claims 19 and 16 of the patent.

Claim 16 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,773,627. Although the conflicting claims are not identical, they are not patentably distinct from each other because The Application's claim is drawn toward a dispersion of cubic liquid crystalline gel particles comprising an amphiphile (comprising a monoglyceride), a polar

solvent and an additive selected from the list wherein the mass fractions are of specified relation. The specification of the Application further includes discussion of hydrotropes and one of ordinary skill in the art would understand the teaching. However the patent is drawn toward a broader invention of a dispersion comprising an amphiphile and a solvent and a hydrotrope wherein the materials are in the same mass fractions as specified by the application and the specification teaches among the amphiphiles the use of monoglycerides (as well as having monoglycerides claimed in this embodiments in claim 14).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

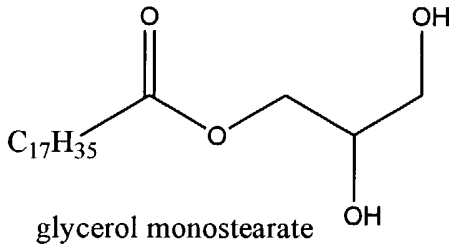
> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 11, 13-17, 19-23, 26-29, 34-38, 41-44, 49-53, 56-59, 64-65, 72-73, and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Akashe et al., U.S. Patent No. 6,274,574 ("Akashe").

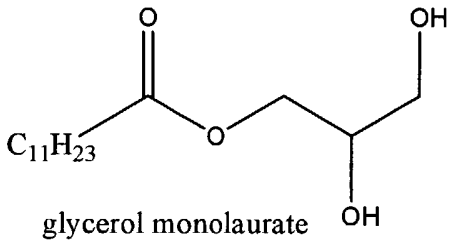
Applicants claim 1 is drawn toward an amphiphile (comprising a monoglyceride) capable of forming a cubic liquid crystalline (LC) phase, a polar solvent, and an additive of either an anchor, tether, or combination thereof and satisfying particular mass fractional requirements. In Applicants' claims 14 and 16 the solvent is a requisite.

Specifically, claim 1 is drawn toward a cubic LC precursor; claim 14 to a bulk cubic LC gel; claim 16 to a dispersion of cubic LC particles and claim 17 toward a method of preparing the precursor of claim 1. The amphiphile of claim 1 is specified in claim 2 to be a monoglyceride of a specified formula.

Akashe teaches use of mesophase-stabilized compositions for delivery of cholesterol-reducing sterols and stanols in food products wherein the compositions contain plant sterols and/or plant esters and a mixture of two or three different emulsifiers (abstract; 5:11-14). Component B of Akashe may be a monoglyceride of the following formulas (10:63-67):



glycerol monostearate



glycerol monolaurate

both of which satisfy Applicants' requirements of the amphiphilic component being a cubic liquid crystalline precursory monoglyceride of the formula shown in Applicants' claim 2. With regard to the specification of an anchor, tether, or combination thereof, an "emulsifier" by definition is a surface-active agent or "surfactant" (Hawley's Condensed Chemical Dictionary, 14th ed.). Examiner notes that assorted surfactants, which are specified in Applicants' claim 4, are listed by Applicants as anchors, thereby satisfying the requirement. Examiner further notes that the difference with regard to a tether and an anchor as defined by the Applicants in merely in the size of

the compound. Thus the Examiner interprets Akashe as teaching both anchors and tethers as the sizes of the materials of Akashe vary.

Component B of Akashe is formulated as either A, B, and C (herein composition 1) and as B and C (herein composition 2). With regard to Applicants' claims 3 and 14, these compositions when mixed with water form cubic mesophases and may form as a gel depending upon the solvent level (9:20-46). The ranges of components fall within Applicants' specified ratios (13:53-14:28).

Claims 11 and 15 are drawn toward an active ingredient being added to the composition. Applicants define "active ingredient" as agrochemicals, pharmaceutical, cosmetic, enzyme, etc (pages 14-15 of Applicants' specification). Examiner notes that *anything* really can be interpreted as an "active ingredient" as really there are few compounds that will never fall within these categories. However, Akashe teaches that a cholesterol-reducing compound is added to the oil phase containing A and B (14:36). Cholesterol reduction is considered both cosmetic and health-conscious/medical. Further, the compounds are indeed carriers of food that is the supplementation of nutrients. Akashe further teaches the compounds for use in food products to make the materials taste and texture more palatable. This is determined to anticipate the limitation of "nutrient delivery" as specified by Applicants' claim 13.

Lastly, these materials are combined a variety of ways. With regard to Applicants' claim 17, Akashe teaches powdered forms of A and B to be dispersed in an oil phase at room temperature and then heated to about 80°C-100°C (14:29-36). With regard to Applicants' claim 19, components A and B may be in powdered form wherein

the coarse emulsion is homogenized via a moderate to high shear device (14:29-47). The stimulus for forming the cubic liquid crystalline dispersion is either the addition of materials, such as the amphiphile or solvent, the subjection of high shear, or either heating or cooling (6:38-7:7).

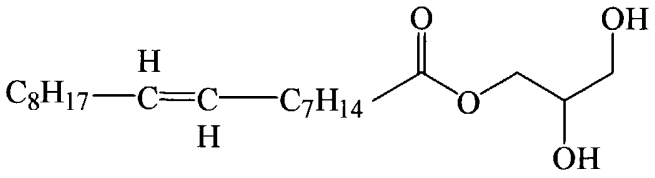
Claims 1-11 and 13-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson, U.S. Patent No. 6,482,517.

Anderson teaches coated particles and methods of making such wherein the particle is coated with a nonlamellar crystalline material including an internal matrix core having at least one nanostructured liquid phase for use as a delivery mechanism of active agents such as pharmaceuticals, nutrients, pesticides and the like (abstract). With regard to Applicants' claim 3, column 6 of Anderson teaches all related polar solvents and moieties, as well as a variety of amphiphiles including surfactants, butanol, and lipids. Preferably Anderson teaches the use of any amphiphile that at very low concentrations lowers interfacial tensions between a polar solvent (such as water) and any hydrophobe (7:54-61). Anderson further teaches, as is discussed in claim 5, that the nonostructured liquid phase comprises a polar solvent, an amphiphile and a surfactant or lipid.

Examiner notes that the surfactant or lipid as taught acts as either an anchor or tether as claimed by Applicants. The surfactants of Anderson anticipate Applicants' claims 4-10 wherein, as Anderson begins in column 9, the surfactants useful in the formation of nonostructured liquid crystalline phases include anionics (negatively charged), cationics (positively charged), zwitterionics (both positively and negatively

charged) and semipolar surfactants. Each of these subheadings includes both anchors and tethers as claimed by the Applicants wherein the surfactants are plant derived or surfactants of biological origin (7:54-61), however Anderson specifically recites the use of block copolymers as tethers (25:54). Furthermore, polybutadien is well known to yield nanostructured liquid crystals (9:55-58) thereby specifically satisfying claims 7 and 9. With regard to claim 8, Anderson teaches preferred surfactants which are FDA-approved as injectables include chitin and cellulose derivatives (26:46-27:36).

With regard to claim 2, Anderson teaches that the preferred amphiphiles include glycerides, aromatic chains, long chain alcohols, aliphatics, low molecular weight hydrophobic polymers and acylated sorbitans (27:37-50). Further, Anderson teaches that the reversed bicontinuous cubic phase does appear in a number of binary systems with single-tailed surfactants, such as those of many monoglycerides (include glycerol monooleate), and a number of nonionic PEG-based surfactants with low HLB (23:22-32). Glycerol monooleate (also known as "monoolein") has the general structure:



Therefore, in accordance with Applicants' expressed monoglyceride, R is C_{17} and is not halogenated. However, it should be noted that additional monoglycerides are anticipated by Anderson. Lastly, it is noted that Anderson teaches the Applicants' expressed mass fractions in the examples.

Claims 1-4, 7-8, 11, 13-18, 20-23, 26-31, 34-38, 41-46, 49-53, 56-61, 64-73, 76-77 and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Engström et al., U.S. Patent No. 5,371,109 ("Engström").

Engström teaches a controlled release composition for a biologically active material dispersed in a cubic liquid crystalline phase comprising at least one monoglyceride of an unsaturated fatty acid; at least one triglyceride (acting as either an anchor or tether) and at least one polar liquid such as water (abstract). The invention of Engström further relates to the encapsulation of a biologically active material, herein known as an "active ingredient" (abstract).

With regard to Applicants' claim 2, Engström teaches the preferred monoglyceride to be monoolein or monolinolein (3:8-10). As noted above, monoolein satisfies the applicants' claimed structure. The ratio of components of Engström is satisfactorily taught (3:33-45), wherein, when the active ingredient is added the active material is present in an amount of 0.1 to 10% by weight although the invention of Engström is not limited to this specific concentration (4:14-17).

The triglycerides of Engström which act as anchors or tethers, depending on the size of the structure, is an unsaturated fatty acid having 16-22 carbon atoms however the triglyceride may be contained in a compositional precursor (3:11-20). Thus, claims 4, 7 and 8 are satisfied.

With regard to claims 17-20, Engström teaches the generic methods as claimed wherein a stimulus is addition dropwise of a solution of active ingredient in order to preserve the structure of the active ingredient (such as is the case when utilizing proteins) (4:32-68). Another stimulus taught by Engström is merely mixing of the components

(5:10-15). Lastly, with regard to Applicants' claim 18, the materials are taught to be aqueous or in liquid form (see examples of Engström).

With regard to Applicants' claim that the materials form a gel, Examiner notes that the definition of a "gel" is merely a colloidal formation. A polymer dispersed liquid crystal (PDLC) in any way, shape, or form satisfies this definition. Thus the Examiner notes that the dispersion of cubic liquid crystals of Engström satisfies this requirement.

Response to Arguments

Applicant's arguments filed 3/24/04 have been fully considered but they are not persuasive. With regard to Akashe the Applicants argue that the compositions of the present invention differ because of the preamble stating that the materials are "suitable for topical application to skin, hair, fabric... for the delivery of pharmaceutical and/or cosmetic active ingredients". Examiner notes that many ingestible compounds- such as strawberries, peaches, egg whites, oatmeal etc- are well known in the cosmetic industry as well as in the food industry. Clearly, there is an overlap between these two industries. Egg whites, for example, are utilized as both a breakfast material, a stiffening agent (such as meringue) and as a facial mask additive for the protein and albumin. Applicants define "active ingredient" as including vitamins and minerals (see claim 27). The Examiner does not believe that there is a difference- either in the art or as defined by the Applicants- between something being "suitable for" application and something "suitable for" eating based on this knowledge.

With regard to Anderson Applicants argue that the invention of Anderson is a coated particle and that such a particle could not read on a "precursor". Examiner

disagrees with this assessment as particles are clearly precursory to a multitude of different materials and compositions depending upon what they are mixed with.

With regard to Engström the Applicants argue that because Engström further includes the use of triglycerides then it cannot be anticipatory. However, Examiner notes that Applicants' use of the phrase "comprising" does not limit the compositions from containing other elements such as triglycerides. Therefore it is unclear how this is a patentable distinction. Applicants arguments are more definitive of a "consisting essentially of" linking statement rather than "comprising" language.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Larsson et al., European Patent No. 0 429 419 teaches an implant material composition comprising an active component of tissue substitute (active ingredient) distributed in a mixture of a water-based liquid (solvent), a monoglyceride (amphiphile) and optionally a triglyceride wherein the mixture is capable of forming into a cubic LC phase when contacted with an aqueous liquid (abstract). The monoglyceride may be a single monoglyceride or a mixture thereof and is generally of an unsaturated fatty acid (6:19-29), wherein especially preferable is the use of monoolein which satisfies Applicants' structure of claim 2. No tether or anchor appears to be taught as triglycerides appear to not fall within Applicants' definition of an anchor or tether. The same holds true for Larsson et al., U.S. Patent No 5,196,201.

The following references all teach monoolein in conjunction with a polar solvent and anchors or tethers for use in forming cubic liquid crystals and drug delivery polymers:

1. Engström et al., "A Study of Polar Lipid Drug Carrier Systems Undergoing a Thermoreversible Lamellar-to-Cubic Phase Transition"

2. Biatry, U.S. Patent No. 6,506,391

3. Engström et al., "Phase Behaviour of the Lidocaine-Monoolein-Water System"

4. Alfons et al., "Drug Compatibility with the Sponge Phases Formed in Monoolein, Water and Propylene Glycol or Poly(ethylene glycol)"

5. Larsson et al., U.S. Patent No 5,196,201

6. Hansen et al., U.S. Patent No 6,228,383

7. Fontell, "Cubic Phases in Surfactant and Surfactant-like Lipid Systems"

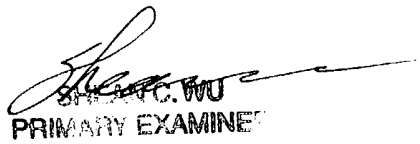
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer R. Sadula whose telephone number is 571.272.1391. The examiner can normally be reached on Monday through Friday, 10am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark F. Huff can be reached on 571.272.1385. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0661.



JRS
August 5, 2004